REMARKS

In the Office Action mailed January 10, 2006 Claims 18, 20, 22-28, 30-36, and 38-41 were pending for consideration in the present application. Each of these claims was rejected under 35 U.S.C. 103(a) as allegedly unpatentable over WO 99/40943 (hereinafter WO '943).

By the present amendment claims 18, 21, 22, 24, and 30-36 have been amended and claim 19, 29, and 37 have been canceled. Support for the amendment of claim 18 can be found in originally filed claim 19, as well as in paragraphs 0002, 0004, 0023, 0024, 0033, 0034, 0050, 0054-0056, 0061, and 0064-0066. Claims 21, 22, and 24 were amended to eliminate the uses of certain terms. Claims 30-36 have been amended to replace the term "crystal" with "particle". Support for this amendment can be found in paragraphs 0007-0012. Therefore, no new matter has been incorporated into the claims. Additionally, it should be understood that such amendments are made solely for the purpose of expediting the prosecution of the present matter and without conceding the correctness of the present rejection. Applicant expressly reserves the right to pursue any canceled or relinquished subject matter in a future continuation application.

The Present Invention

The method recited by the presently pending claims involves a process for preparing micro- and nano-particles of a drug coated with a surfactant. Such a process generally includes the steps of melting an amount of the drug in a molten surfactant miscible with the drug to form a drug-surfactant mixture; heating the mixture to a temperature above the mixture's melting point but below the decomposition temperature of the drug, and to which a clear mixture is formed; and subsequently cooling the mixture to approximately room temperature while continuously mixing under high shear so as to maximize formation of drug particles coated with the surfactant. The goal of such process is to impart improved solubility to the drug particles, and in fact, Applicant's testing results as contained in the examples of the present specification show that the coated drug particles do in fact, have a greater rate of dissolution than pure unprocessed drug.

Rejections Under 35 U.S.C. § 103

The Examiner has rejected claims 18, 20, and 22-38 under 35 U.S.C. 103(a) as allegedly being unpatentable over WO '943. The Applicant respectfully submits that these claims are patentable over the cited reference for the reasons set forth below, and that the rejection should be withdrawn.

While Applicant assumes that the Examiner is well versed in the elements required to establish a *prima facie* case of obviousness, Applicant would like to take this opportunity to briefly summarize this standard. Essentially, in order to establish a *prima facie* case of obvious, the Examiner must meet the burden of showing: 1) that the reference as modified or combined teaches or suggests all of the claim elements; 2) that there is sufficient motivation within the reference itself to make the modification or combination asserted; and 3) that such modification or combination is likely to be successful.

WO '943 teaches a delivery system and related process for enhancing the solubility of poorly soluble drugs. The process as disclosed combines at least one active ingredient with at least one solubilizing agent at a low temperature "in the presence of forces sufficient to produce an active/solubilizer eutectic which is at least partially coated onto or in intimate contact with, particles of the active." WO '943 does not teach "melting" the drug in a molten surfactant as asserted by the Examiner

in the Office Action mailed January 10, 2006, page 2, last paragraph, , and certainly does not teach or suggest heating the mixture until a "clear solution: is formed. Applicant asserts that such a teaching is not in the reference and that the Examiner has misunderstood the reference.

In fact, the cited reference repeatedly teaches away from such an action. For example, page 4, lines 11-16 of WO '943 reads:

> If the blend of ingredients is heated too far above the point at which the eutectic alloy forms, however, it is believed that crystals of the active ingredient dissolve in the solubilizer, or melt, resulting in a saturated or even super saturated solution. Upon cooling the dissolved or melted active will then re-crystallize into crystals which are too large to benefit from improved wetting of the solubilizer/eutectic coating and not dissolve as readily. (emphasis added)

In essence WO '943 teaches that if the drug is melted in the solubilizer (or in the present case the surfactant) the purpose of the whole process is defeated, namely the enhanced solubility benefits are destroyed. It is important to note that in the above passage, the term "melt" is used as a synonymously with "dissolve in the solubilizer." This teaching is further elaborated on in the specification on page 5, lines 25-30 which read:

> In addition, it is preferable that there be sufficient "head room" between the solubilizer melt temperature and the active melt temperature to enable one to process the combination at a temperature sufficiently low such that the active does not dissolve [melt] in the solubilizer. It is believed that if too much of the active ingredient dissolves in the eutectic, upon cooling the active will form crystals which will be so large that the cannot benefit from the wetting effects of the solubilizer and therefore, not dissolve as readily. (Emphasis added)

This idea is again reiterated on page 6, lines 20-25 which reads:

> Preferably the temperatures at which the ingredients are contacted are below the formation point of the combination's eutectic to below the temperature at which the active will dissolve in the solubilizer so that the drug does not totally dissolve [melt] in the eutectic. When temperatures are too high, one or both of the ingredients can, upon cooling crystallize too quickly, resulting crystal reformation which are too large to take advantage of the wetting properties of the solubilizer/eutectic.

Based on the above listed passages, it is clear that not only does WO' 943 fail to teach each and every element of the currently pending claims, namely melting the drug in the surfactant, it also repeatedly teaches away from such a method.

In addition, the presently pending claims require that the drug surfactant mixture be heated to a temperature which is higher than the temperature levels taught in WO '943. Before continuing, the Examiner is invited to revisit the Applicant's arguments regarding the processing temperatures presented in the previous office action submitted on 10-21-05. In response to those arguments the Examiner has asserted that the teaching in WO '943 that the mixtures are heated to "temperatures below the melting points of both" (see page 2 lines 21-21) is sufficient to render obvious all temperatures which are above the mixture's melting point but below the decomposition temperature of the drug. The Applicant argues that such an assertion is incorrect.

The specification of WO '943 gives further limitation to the upper temperature range for use in its invention. On page 6, lines 26-28 the specification states:

> Typical temperatures used in the invention range from at or below the standard eutectic formation temperature to **below** the temperature at which the active melts or readily dissolves in the solubilizer. (emphasis added)

In essence this statement sets forth a maximum temperature which can be used in the process disclosed in WO '943 which, when read broadly, can include temperatures up to just below the melting point of the drug. As stated previously, presently pending claim 18 requires the "melting" of the drug in the molten surfactant. This requirement inherently requires that the temperature of the process be at a high enough temperature to melt the drug, something that WO '943 expressly excludes or prohibits. By requiring the melting of the drug into the surfactant, the present invention goes directly contrary to the teachings of WO '943, or in other words, WO '943 teaches away from the use of temperatures high enough to melt the drug.

As WO '943 fails to provide any motivation or suggestion to be modified in a manner that would teach or suggest the present invention, and in fact, repeatedly teaches away from the claimed method, Applicant respectfully submits it does not render the present invention obvious and does not constitute a *prima facie* case of obviousness. Therefore, it is respectfully requested that the rejection be withdrawn.

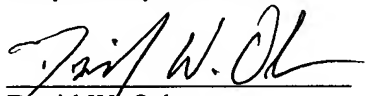
CONCLUSION

In view of the foregoing, Applicants believe that pending claims 18, 20, 22-28, 30-36, and 38 present allowable subject matter and allowance thereof is respectfully requested. If any impediment to the allowance of these claims remains after consideration of the above remarks, and such impediment could be removed during a telephone interview, the Examiner is invited to telephone the undersigned attorney at (801) 566-6633 so that such issues may be resolved as expeditiously as possible.

Please charge any additional fees except for Issue Fee or credit any overpayment to Deposit Account No. 20-0100.

Dated this 10th day of April, 2006.

Respectfully submitted,



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